REMARKS

Claims 126-128, 131, 144, 149-150, 157, 159-172 were pending in the application. Claims 128 and 162 have been cancelled and claims 126, 144, 160-161 and 163-164 have been amended. Accordingly, after the amendments presented herein have been entered, claims 126-127, 131, 144, 149, 150, 157, 159-161 and 163-172 will be pending.

Claims 126, 160, 161, 163 and 164 have been amended to correct grammatical and typographical errors and to clarify the invention. Claim 159 has been amended to correct claim dependency. Applicants respectfully submit that no new matter has been introduced by the foregoing amendments.

Amendment and/or cancellation of the claims is not to be construed as acquiescence to any of the objections/rejections set forth in the instant Office Action or any previous Office Action of the parent application, and was done solely to expedite prosecution of the application. Applicants reserve the right to pursue the claims, as originally filed or similar claims in this or one or more subsequent patent applications.

Acknowledgment of Examiner's Withdrawal of Previous Rejections

Applicants gratefully acknowledge the Examiner's withdrawal of the following: (a) the previous rejection of claim 128 under 35 U.S.C. § 112, second paragraph, (b) the previous rejection of claim 159 under 35 U.S.C. § 112, second paragraph, (c) the previous rejection of claims 126-128, 131, 144, 149, 150, 157 and 159 under 35 U.S.C. § 112, first paragraph, (d) the previous rejection of claims 128, 144, 159 and 162-164 under 35 U.S.C. § 112, first paragraph, (e) the previous rejection of claim 144 under 35 U.S.C. § 112, second paragraph, and (f) the previous rejection of claim 162 under 35 U.S.C. § 112, second paragraph.

Objection(s) to Specification

The Examiner has objected to the specification with regard to claims 128 and 162. Claim 128 was directed to a method of resuscitating dormant moribund or latent high G+C Gram-positive bacterial cells according to claim 126 or 127, wherein said dormant, moribund or latent high G+C Gram-positive bacterial cells are present in a sample, and the method identifies the presence of dormant, moribund or latent high G+C Gram-positive bacterial cells in the sample by detecting growth of high G+C Gram-positive bacterial cells in the sample. Claim 162 was directed to a method of resuscitating dormant moribund or latent high G+C Gram-positive bacterial cells according to claim 160 or 161, wherein said dormant, moribund or latent high G+C Gram-positive bacterial cells are present in a sample, and the method identifies the presence of dormant, moribund or latent high G+C Gram-positive bacterial cells in the sample by detecting growth of high G+C Gram-positive bacterial cells in the sample.

The Examiner is of the opinion that the last two lines of both claims do not contain the limitation the is present in the earlier part of the claims and that requires the high G+C Gram positive bacterial cells to be dormant, moribund or latent. The Examiner also argues that there is no antecedent basis for a method of resuscitating dormant moribund or latent G+C Gram-positive bacterial bacterial cells, wherein the resuscitating method concurrently serves as a method of specifically identifying dormant moribund or latent G+C Gram-positive bacterial cells in a generic sample, or in a sample from a human or an animal.

Applicants respectfully traverse the above objection. Nonetheless, solely in the interest of advancing prosecution and without acquiescing to the Examiner's objection, claims 128 and 162 have been cancelled, without prejudice. Accordingly, Applicants respectfully request reconsideration and withdrawal of the objection to the specification.

Rejection of Claims 128 and 159-162 under 35 U.S.C § 112, First Paragraph

Claims 128 and 159-162 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The Examiner is of the opinion that

> …lines 24-28 of page 2 of the specification do not provide descriptive support for the now claimed method of claim 128 or 162, i.e., the method of stimulating growth of high G+C Gram-positive bacterial cells or the method of resuscitating dormant, moribund or latent high G+C Gram-positive bacterial cells comprising contacting the cells present in a sample in vitro and incubating the cells in culture medium containing the recited polypeptide serving also as a method of identifying specifically the presence of 'dormant, moribund or latent high G+C Gram-positive bacterial cells in the sample by detecting growth of high G+C Gram-positive bacterial cells in the sample'. Nowhere does the specification, as originally filed, equate demonstrating renewed culturability of dormant, moribund or latent bacterial cells to a method of identifying dormant, moribund or latent high G+C Gram-positive bacterial cells in a sample via 'detecting growth of high G+C Gram-positive bacterial cells in the sample. See also paragraph 7 supra. Therefore, the identified limitation(s) in the claims(s) and the currently claimed scope of the claims constitute new matter.

Applicants respectfully traverse the above rejection. Nevertheless, solely in the interest of expediting prosecution and in no way acquiescing to the Examiner's rejection, claims 128 and 162 have been cancelled without prejudice and claim 159 has been amended to depend from claim 126, thereby rendering the Examiner's rejection as it relates to these claims moot.

Rejection of Claims 160 and 161

Claims 160 and 161 have also been rejected under 35 U.S.C § 112, First Paragraph, however, no explanation for this rejection was given in the Office Action. In contrast to claims 128, 159 and 162, claims 160 and 161 are not directed to a method of identifying presence of dormant, moribund or latent high G+C Gram positive bacterial cells in the

sample by detecting growth of high G+C Gram positive bacterial cells in the sample. Applicant believes that this rejection may have been made in error. Accordingly, Applicant respectfully requests that the rejection of claims 160 and 161 under 35 U.S.C § 112, First Paragraph be withdrawn or that an explanation for this rejection be given for the record.

Rejection of Claims 126-128, 131, 144, 149, 150, 157, 159-164 and 167 under 35 U.S.C § 112, Second Paragraph

Claims 126-128, 131,144, 149, 150, 157, 159-164 and 167 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. With respect to claims 128 and 162, it was further stated in the Office Action that these claims are indefinite and confusing in the method wherein 'the method identifies the presence of dormant, moribund or latent high G+C Gram-positive bacterial cells in the sample by detecting growth of high G+C Gram-positive bacterial cells in the sample'.

Applicants thank the Examiner for the suggestions of how to respond made in paragraph 21 (a) of the Office Action. Applicants have amended claims 126, 144, 160, 161, 163 and 164 in line with these suggestions. Specifically, Applicants have amended claim 126 by replacing the limitations 'high G+C Gram-positive bacterial cells' in lines 4 and 7, 'dormant, moribund or latent high G+C Gram-positive cells' in lines 4 and 8, and 'growth' in line 12 with the limitations 'the high G+C Gram-positive bacterial cells', 'the dormant, moribund or latent high G+C Gram-positive cells', as suggested by the Examiner. Similar amendments have been made to claims 144, 160, 161, 163 and 164, thereby rendering these rejections moot. With respect to claims 128, 159 and 162, Applicants respectfully submit that cancellation of these claims renders the above rejection moot.

Rejection of Claims 125, 127, 131 and 144 under 35 U.S.C. § 102(b)

Claims 126, 127, 131 and 144 have been rejected under 35 U.S.C. § 102(b) as being anticipated by of Mukamolova *et al. (Antonie van Leeuwenhoek* 67: 289-295, 1995, of record) (Mukamolova *et al.,* 1995) as evidenced by Mukamolova *et al. (PNAS* 95: 8916-8921, July 1998, of record) (Mukamolova *et al.,* 1998). The Examiner is of the opinion that

> [M]ukamolova et al. (1995) taught a method of resuscitation of starved or dormant cells present in stationary culture samples of Micrococcus luteus, a high G+C Gram positive bacterium, by contacting the dormant cells with a sterile-filtered supernatant isolated from the late log phase of viable cultures of the same high G+C Gram positive Micrococcus luteus, which supernatant contains an antibacterial factor secreted or expressed by the Micrococcus luteus cells, or by contacting with the resuscitating cell strain of Micrococcus luteus secreting or expressing an antibacterial factor, and incubating.

The Examiner also states that, because the strain of viable and dormant Micrococcus luteus used by Mukamolova *et al.* (1995) is the same strain used in the instant invention by the Applicants, the prior art strain is expected to necessarily secrete or express an at least 50% identical polypeptide of the instantly recited polypeptide comprising amino acid residues 117 to 184 of SEQ ID NO:2. Specifically, it is alleged in the Office Action that

> [t]he prior art method meets the recited steps (i) and (ii) of the instant claims and therefore necessarily identifies the presence of high G+C Gram positive Micrococcus luteus cells by detecting their growth. The limitation 'recombinant' in claim 127 represents a process limitation. A product does not have to be made by the same process in order to be the same product. In the instant case, Applicants have not shown the underlying structure of the prior art polypeptide differs from that of the instantly recited polypeptide.

Applicants respectfully traverse this rejection on the grounds that Mukamolova *et al.* (1995) fail to anticipate claims 126, 127, 131 and 144 because Mukamolova *et al.* (1995) fail to teach or suggest each and every element of the claims.

For a prior art reference to anticipate a claimed invention, the prior art must teach ***each and every element of the claimed invention***. *Lewmar Marine v. Barient*, 827 F.2d 744, 3 USPQ2d 1766 (Fed. Cir. 1987) (emphasis added).

Applicants respectfully draw the Examiner's attention to the fact that the antibacterial factor described by Mukamolova *et al.* (1995) is not the RP factor of the presently claimed invention. Moreover, the antibacterial factor described by Mukamolova *et al.* (1995) has biological properties that are very different from those of the RP factors of the presently claimed invention. Mukamolova *et al.* (1995) observe that growth of Micrococcus luteus cells harvested in the late logarithmic phase is inhibited by addition of resuscitating Micrococcus luteus cells (see abstract; page 291, column 2, lines 16-21; Figure 2.) Growth of Micrococcus luteus cells harvested in the late logarithmic phase is similarly inhibited by the filtered supernatant isolated from the resuscitating cultures (see page 292, column 2, lines 9-17; Figure 2). Mukamolova et al. (1995) conclude that inhibition of growth of Micrococcus luteus cultures is caused by a secreted factor. This factor is secreted by the resuscitating Micrococcus luteus cells (*i.e.*, not late log phase Micrococcus luteus cultures) and acts to inhibit growth of Micrococcus luteus.

In contrast, the RP factors of the presently claimed invention have a biological activity which is the opposite of the biological activity of the antibacterial factor described by Mukamolova *et al.* (1995). The RP factors of the claimed invention are produced by the late logarithmic phase Micrococcus luteus cells (see specification, page 45, line 23), not by the resuscitating Micrococcus luteus cells that have not yet entered logarithmic growth. The RP factors act to stimulate growth of G+C Gram-positive bacterial cells or to resuscitate dormant, moribund or latent G+C Gram-positive bacterial cells, as is described at page 4, lines 5-10 of the specification.

Because the antibacterial factor disclosed by Mukamolova *et al.* (1995) exhibits biological activity that is the opposite of the biological activity exhibited by the RP factors of the instant invention and required by the pending claims, the antibacterial factor described by Mukamolova *et al.* (1995) is not the RP factor that is the subject of the pending claims (*i.e.*, not the polypeptide having at least 50% sequence identity with amino acid residues 117 to 184 of SEQ ID NO:2). Accordingly, Mukamolova *et al.* (1995) fail to teach or suggest each and every element of claim 126 and claims dependent therefrom.

With respect to claim 144, Mukamolova *et al.* (1995) fail to describe the limitation in part (ii) of the claim, wherein the method results in stimulation of growth of high G+C Gram-

positive bacterial cells or in resuscitation of dormant, moribund or latent high G+C Gram-positive bacterial cells. Accordingly, Mukamolova *et al.* (1995) also fail to anticipate claim 144 and claims dependent therefrom.

Furthermore, even if the antibacterial factor disclosed by Mukamolova et al. were the same as the RP factor of the presently claimed invention, which the Applicants unequivocally dispute, Applicants respectfully submit that Mukamolova et al. would still fail to describe each and every element of claim 126, 144 and claims dependent therefrom. Claim 126 is directed to a method of stimulating growth of high G+C Gram-positive bacterial cells or of resuscitating dormant, moribund or latent high G+C Gram-positive bacterial cells, wherein in in part (i) the method comprises contacting the high G+C Gram-positive bacterial cells in vitro with an isolated polypeptide having at least 50% sequence identity with amino acid residues 117 to 184 of SEQ ID NO:2. The term "isolated", when applied to an RP factor, is defined at page 18, lines 4-9 of the specification as meaning that "the RP factor exists in a physical milieu distinct from that in which it occurs in nature. For example, the isolated factor may be substantially isolated with respect to the complex cellular milieu in which it naturally occurs." Mukamolova *et al.* (1995) describe factors that are present in the culture media or in the filtered supernatant, both of which represent a natural milieu for the antibacterial factor. Accordingly, the antibacterial factor is not isolated and is, therefore, different from the isolated polypeptide required by claim 126 and claims dependent therefrom.

For the reasons stated above, Applicants respectfully submit that Mukamolova *et al.* (1995) fail to teach or suggest each and every element of the instant claims 126, 127, 131 and 144, and the pending claims. Thus, the pending claims are novel and inventive over Mukamolova *et al.* (1995). Applicants respectfully request reconsideration and withdrawal of the present rejection.

Claim Objections

Claim 160 has been objected to for the unnecessary and/or confusing notation "-" before the limitation "wherein" in line 6 of the claim. Claims 161 and 163 have also been

objected to for the notation "-" at the end of line 6 in between the limitations "NO:" and "2" of claim 161 and in line 6 of claim 163.

Applicants respectfully submit that claims 160, 161 and 163 have been amended to remove the notations listed above. Accordingly, Applicants respectfully request that the foregoing objection be reconsidered and withdrawn.

CONCLUSION

If a telephone conversation with Applicants' Attorney would expedite the prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 449-6500.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-4876, under Order No. 118160-00301.

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Respectfully submitted,

By /MLZ/

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